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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/921,655      | 08/03/2001  | Michael H. Cardone   | M00925/70106        | 5833             |

23628 7590 04/08/2003

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| EXAMINER |
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CHEU, CHANGHWA J

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| ART UNIT | PAPER NUMBER |
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1641

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DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/921,655

Applicant(s)

CARDONE ET AL.

Examiner

Jacob Cheu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 11-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of group I, claims 1-10, is acknowledged.
2. The traversal is on the ground(s) that the additional search will not impose an undue burden on the examiner. This is not found to be persuasive because each group acquires separate classifications with diverse literature search. Therefore, the requirement is still deemed proper and is therefore made **FINAL**.

### *Priority*

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) to the U.S. provisional application 60222763 is acknowledged. However, the U.S. provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claim 10 of this application. While the instant application claims the said microarray has *at least 2000 spots* per  $\text{cm}^2$ , the provisional application fails to provide adequate support because on page 3, fourth paragraph, the provisional application shows the density of *at least 1000 spots* per  $\text{cm}^2$ , and on page 12, third paragraph, the provisional application shows that the density is about *1600 spots* per  $\text{cm}^2$ . Therefore, the provisional application does not support the scope the instant claim 10. Thus, claim 10 is accorded priority to the current application (US 09/921655) on 8/3/2000.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1, 3, 4, 7, 9 and 10 are rejected under 35 U.S.C. 102 (a) as being anticipated by MacBeath et al. (J. Am. Chem. Soc. (1999) 121: 7967-7968)

MacBeath et al teach an array device comprising a glass solid support where the surface on the glass has been functionalized with maleimide group. (Page 7967, Right column, second paragraph) MacBeath et al. teach using a linker covalently attached to the glass surface. (See Figure 1) The linker can interact with a compound, forming a linker derivative which subsequently can bind to the protein of interest via covalent binding, i.e. sulfhydryl group which can form covalent bond with the target protein through 2-mercaptoethanol blocking. (Page 7967, Right column, third paragraph) MacBeath et al. also teach using antibody fluorescence-linked assay to detect ligand-protein binding. (supra. Last paragraph) The dimension of the microarray in MacBeath et al. is more than 2000 spots per  $\text{cm}^2$ . (Figure 4)

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 2, 5, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacBeath et al. in view of Wagner et al. (USP 6475808).

MacBeath et al reference has been discussed supra but does not specifically teach use of vinylsulfone group and N-hydroxy succinimide group for the linker. In addition MacBeath et al are silent in teaching forming a covalent bond between the protein, protein fragment or single chain antibody and the linker. Wagner et al. teach a protein screening assay where the array has monolayer linker comprising N-hydroxysuccinimide, vinylsulfone or carboxyl functional moiety for reaction (Col. 16, line 62-68; Col. 17, line 1-6), and a linkage formation through carboxy terminus on the protein. (Col. 8, line 48-54) Wagner et al. also teach using single chain antibody (scFv, Col. 24, line 18-22) for the protein screening assay. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of MacBeath et al. with the other choices of functional moiety on the solid support and the single chain antibody as taught by Wagner et al. since both MacBeath and Wagner et al. reference are analogous in solving problems of functionalizing solid surface and use of protein array detection.

#### ***Conclusion***

6. No claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

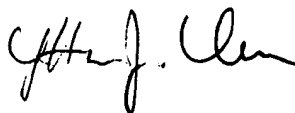
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu

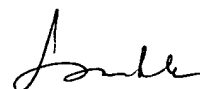


Examiner

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April 2, 2003



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

04/02/03